



## Proposed Regulation Agency Background Document

<b>Agency name</b>	Board of Dentistry, Department of Health Professions
<b>Virginia Administrative Code (VAC) citation</b>	18VAC60-20-10 et seq.
<b>Regulation title</b>	Regulations Governing the Practice of Dentistry and Dental Hygiene
<b>Action title</b>	Requirements for registration and practice of mobile dental clinics and portable dental operations
<b>Date this document prepared</b>	March 23, 2010

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 36 (2006) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

### Brief summary

*In a short paragraph, please summarize all substantive provisions of new regulations or changes to existing regulations that are being proposed in this regulatory action.*

The budget bills (HB1600 and SB950) of the 2009 Acts of the Assembly required the Board of Dentistry to revise its regulations to provide for registration of mobile dental clinics and portable dental operations. The legislation further required that the Board promulgate regulations to implement the provisions of the act to be effective within 280 days of its enactment, so emergency regulations were authorized under the Administrative Process Act and became effective January 8, 2010.

The intent of the regulatory action is compliance with the statute that requires the Board to establish regulations for registration of mobile dental clinics and portable dental operations. Regulations include definitions of terminology used, requirements for registration, reporting requirements by providers, and other requirements to ensure accountability of care for services rendered.

## Legal basis

*Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., the agency, board or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.*

Regulations are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400, which provides the Board of Dentistry the authority to promulgate regulations to administer the regulatory system:

**§ 54.1-2400 -General powers and duties of health regulatory boards**

*The general powers and duties of health regulatory boards shall be:*

...

*5. To levy and collect fees for application processing, examination, registration, certification or licensure and renewal that are sufficient to cover all expenses for the administration and operation of the Department of Health Professions, the Board of Health Professions and the health regulatory Boards.*

*6. To promulgate regulations in accordance with the Administrative Process Act (§ 9-6.14:1 et seq.) which are reasonable and necessary to administer effectively the regulatory system. Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 (§ [54.1-100](#) et seq.) and Chapter 25 (§ [54.1-2500](#) et seq.) of this title. ...*

The specific mandate to promulgate regulations for the registration of mobile dental clinics is found in the 2009 budget bill:

*“B. Notwithstanding the provisions of Chapter 27 of title 54.1 of the Code of Virginia, the Board of Dentistry shall revise its regulations pertaining to the licensure of dentists and dental hygienists to require that mobile dental clinics and other portable dental operations meet certain requirements to ensure that patient safety is protected, appropriate dental services are rendered, and needed follow-up care is provided. The revised regulations shall include, but not be limited to requirements for registration by the mobile clinics, locations where services are provided, reporting requirements by providers and other regulations to insure accountability of care rendered. These regulations shall apply to all mobile dental facilities or portable dental programs with the exception of those operated by federal, state or local governmental agencies, or by other entities deemed appropriate for exemption by the Board of Dentistry. The Board shall promulgate regulations to become effective within 280 days or less from the enactment of this act to implement these changes.”*

The 2010 General Assembly has passed HB308, which adds a section to Chapter 27 of Title 54.1 to authorize regulation of mobile dental clinics, as follows:

*§ [54.1-2708.3](#). Regulation of mobile dental clinics.*

*No person shall operate a mobile dental clinic or other portable dental operation without first registering such mobile dental clinic or other portable dental operation with the Board, except that mobile dental clinics or other portable dental operations operated by federal, state, or local*

*government agencies or other entities identified by the Board in regulations shall be exempt from such registration requirement.*

*The Board shall promulgate regulations for mobile dental clinics and other portable dental operations to ensure that patient safety is protected, appropriate dental services are rendered, and needed follow-up care is provided. Such regulations shall include, but not be limited to, requirements for the registration of mobile dental clinics, locations where services may be provided, requirements for reporting by providers, and other requirements necessary to provide accountability for services rendered.*

## Purpose

*Please explain the need for the new or amended regulation by (1) detailing the specific reasons why this regulatory action is essential to protect the health, safety, or welfare of citizens, and (2) discussing the goals of the proposal, the environmental benefits, and the problems the proposal is intended to solve.*

To protect the health and safety of persons served in mobile dental clinics, amendments to Chapter 20 require registration to include information about where and when the practices will be operating and which practitioners will be providing care. The clinics must also certify to agreements for follow-up care, emergency contact arrangements, access to all essential equipment and conformity to laws and regulations. There must be written consent to dental care in a mobile clinic, and patients must be provided with an information sheet that details who provided treatment, a description of the treatment and any additional dental needs, a recommendation or referral for follow-up care, and emergency contact information. Such requirements are necessary to ensure that patients (often school children) are not left with unresolved dental problems or with little or no information about what was done during a visit by a mobile clinic. Finally, regulations stipulate that the same rules and standards of care apply for practice in a mobile clinic as in a fixed facility.

## Substance

*Please briefly identify and explain new substantive provisions (for new regulations), substantive changes to existing sections or both where appropriate. (More detail about all provisions or changes is requested in the "Detail of changes" section.)*

The key provisions of the regulations are: 1) establishment of definitions of a "mobile dental clinic" and a portable dental operation;" 2) requirements for registration including information on locations, dates and practitioners providing services, certifications of agreements for follow-up care and access to emergency care, certification of availability of certain equipment and resources, and conformity to operational and permitting standards; 3) requirements for operation of the clinic, including posting of licenses, written consent for treatment, information on treatment and needed follow-up for patients, and maintenance of patient records; and 4) exemptions from the requirements for registration for governmental agencies and periodic volunteer clinics providing free care.

**Issues**

*Please identify the issues associated with the proposed regulatory action, including:*  
 1) *the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;*  
 2) *the primary advantages and disadvantages to the agency or the Commonwealth; and*  
 3) *other pertinent matters of interest to the regulated community, government officials, and the public.*

*If the regulatory action poses no disadvantages to the public or the Commonwealth, please so indicate.*

- 1) The primary advantage to the public is more accountability for mobile dental clinics providing services to school children and others in Virginia. Information on practitioners and locations, appropriate procedures for follow-up care and emergencies and adequate equipment for such clinics will provide some assurance that the care being given is safe and competent. The disadvantage could be that the registration process may discourage some clinic operations from coming into Virginia, thus reducing access to care. In passing the mandate for registration, members of the General Assembly determined that the advantages for greater protection in dental care outweighed the potential for any loss of access.
- 2) There are no advantages or disadvantages to the Commonwealth; the Board set the application and renewal fee with the goal of covering expenditures related to registration of mobile dental clinics.
- 3) There are no other pertinent matters of interest.

**Requirements more restrictive than federal**

*Please identify and describe any requirement of the proposal, which are more restrictive than applicable federal requirements. Include a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.*

There are no applicable federal requirements.

**Localities particularly affected**

*Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.*

There are no localities particularly affected by the proposed regulation.

**Public participation**

*Please include a statement that in addition to any other comments on the proposal, the agency is seeking comments on the costs and benefits of the proposal and the impacts of the regulated community.*

In addition to any other comments, the board/agency is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal. Also, the agency/board is seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) probable effect of the regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit written comments may do so via the Regulatory Townhall website, [www.townhall.virginia.gov](http://www.townhall.virginia.gov), or by mail, email or fax to Elaine Yeatts at Department of Health Professions, 9960 Mayland Drive, Suite 300, Richmond, VA 23233, or [Elaine.yeatts@dhp.virginia.gov](mailto:Elaine.yeatts@dhp.virginia.gov) or by fax to (804) 527-4434. Written comments must include the name and address of the commenter. In order to be considered comments must be received by the last date of the public comment period.

A public hearing will be held and notice of the public hearing may appear on the Virginia Regulatory Town Hall website ([www.townhall.virginia.gov](http://www.townhall.virginia.gov)) and the Commonwealth Calendar. Both oral and written comments may be submitted at that time.

**Economic impact**

*Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact.*

<p><b>Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source, and (b) a delineation of one-time versus on-going expenditures.</b></p>	<p>a) As a special fund agency, the Board must generate sufficient revenue to cover its expenditures from non-general funds, specifically the renewal and application fees it charges to practitioners for necessary functions of regulation; b) The agency will incur some one-time costs (less than \$1,000) for mailings to the Public Participation Guidelines mailing lists and conducting a public hearing. Every effort will be made to incorporate those into anticipated mailings and meetings already scheduled; on-going expenditures related to registration of such clinics or operations will be offset by application and renewal fees generated.</p>
<p><b>Projected cost of the new regulations or changes to existing regulations on localities.</b></p>	<p>There is no cost on localities.</p>
<p><b>Description of the individuals, businesses or other entities likely to be affected by the new regulations or changes to existing regulations.</b></p>	<p>Persons or entities who want to operate a mobile dental clinic or portable dental operation in Virginia.</p>

<p><b>Agency’s best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected.</b> Small business means a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.</p>	<p>There is currently one mobile dental clinic registered to do business and one pending application. It is unlikely that the number of registrants would exceed five or six. All would be small businesses.</p>
<p><b>All projected costs of the new regulations or changes to existing regulations for affected individuals, businesses, or other entities. Please be specific and do include all costs. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses. Specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.</b></p>	<p>Costs of new regulations on operators of mobile dental clinics would include an application fee of \$250 and an annual renewal fee of \$150. The costs for recordkeeping and administration of the clinic are not known, but the requirements of regulations are consistent with other states in which these clinics operate and consistent with an acceptable standard of care.</p>
<p><b>Beneficial impact the regulation is designed to produce.</b></p>	<p>The beneficial impact is accountability for the dental services being provided and some assurance that follow-up care has been arranged.</p>

**Alternatives**

*Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in §2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.*

There are no alternatives to the promulgation of regulations, which were required by the budget bills of the 2009 Acts of the Assembly and by HB308 passed by the 2010 General Assembly.

On April 22, 2009, the Regulatory/Legislative Committee reviewed a draft of regulations that was based on provisions of the law in Virginia and on requirements found in other states. The budget bill specified the subject areas regulations must include – requirements for registration, locations where services are provided, reporting requirements, and other regulations to ensure accountability of care. In addition, regulations, laws and application forms in Texas, Kansas, Tennessee, South Carolina, Indiana and Mississippi were used as a basis for draft regulations. The Committee recommended those requirements it believed were necessary to ensure accountability, access to records, continuity of care and safe dental practice.

In the adoption of proposed regulations, the Board was able to clarify certain provisions, correct an oversight on the renewal deadline, and eliminate several provisions that were unnecessary or could be burdensome.

**Regulatory flexibility analysis**

*Please describe the agency’s analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.*

Since the registration and regulation of mobile dental clinics and portable dental operations were mandated by Virginia law, the Board determined that there were no alternatives other than the promulgation of regulations.

**Public comment**

*Please summarize all comments received during public comment period following the publication of the NOIRA, and provide the agency response.*

<b>Commenter</b>	<b>Comment</b>	<b>Agency response</b>
Terry Dickinson, DDS for the Virginia Dental Association	The Virginia Dental Association is in support of the emergency regulations concerning the use of mobile dental vans providing dental services to areas within the Commonwealth. We feel that the regulations are necessary to protect the public and to make sure that the for-profit mobile clinics are held to the same standards as fixed based dental operations. The goal of these mobile clinics should be, above all, to make sure that the children seen are connected to a 'dental home'. We feel that these regulations do that and do provide adequate safety requirements and responsibilities to assure quality of care to the children seen by these clinics.	The agency concurs with the comment.
Dr. Joseph Mix	Requested an addition to the exemptions for registration to include emergency dental care to adults in their homes	The Board did not amend the regulations because it does not consider the provision of emergency dental services in homes to be the use of a mobile dental clinic or portable dental operation.

**Family impact**

*Please assess the impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one’s spouse, and*

one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

There is no potential impact on the institution of the family.

**Detail of changes**

*Please detail all changes that are being proposed and the consequences of the proposed changes. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact if implemented in each section. Please detail the difference between the requirements of the new provisions and the current practice or if applicable, the requirements of other existing regulations in place.*

*If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all provisions of the new regulation or changes to existing regulations between the pre-emergency regulation and the proposed regulation, and (2) only changes made since the publication of the emergency regulation.*

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
10	n/a	Sets out definitions for words and terms used in the regulation	Definitions are added for a mobile dental clinic and a portable dental operation. <i>The definitions are consistent with those used in the other states that also regulate such entities.</i>
30	n/a	Establishes certain fees charged to entities the Board regulates	An application fee of \$250 is established for registration of clinics or operations, and an annual renewal fee is set at \$150. <i>Each application will be quite detailed and require a thorough review by staff and possibly one or more board members. A number of certifications are required, as well as information on ownership and operation of the facility. In addition, the regulation requires that the entity provide revisions to the information on locations and dates and on the dentists, dental hygienists or dental assistants II who will be providing dental services at least 10 days prior to the provision of such services. Therefore, there will be a need for constant review and updating of the registration application and renewal. The board has attempted to adopt a minimal fee consistent with its mandate to cover expenses with the fees it charges to regulated entities. In regulations in other states where mobile clinics are also registered, the fees range from \$500 application in Kansas to \$50 in Texas.</i>  <b><i>Changes from the emergency regulations:</i></b>

			In the proposed regulations, an oversight was corrected with the inclusion of a due date for renewal of December 31 <sup>st</sup> and a late fee of \$50 for renewal fees received after that date.
n/a	332	Establishes the requirements for registration	<p>Subsection A sets out the information to be included on an application for registration, including:</p> <ol style="list-style-type: none"> <li>1. The name and address of the owner of the facility or operation and an official address of record for the facility or operation, which shall not be a post office address. Notice shall be given to the board within 30 days if there is a change in the ownership or the address of record for a mobile dental facility or portable dental operation;</li> </ol> <p><i>In order to ensure access to patient records in case of a complaint to the Board or if requested by the patient or another practitioner, there must be a permanent address from which the records can be obtained and the name of an owner who is responsible for the facility's or operation's compliance with laws and regulations..</i></p> <ol style="list-style-type: none"> <li>2. The name, address and license number of each dentist and dental hygienist or the name, address and registration number of each dental assistant II who will provide dental services in the facility or operation. The identity and license or registration number of any additional dentists, dental hygienists or dental assistants II providing dental services in a mobile dental facility or portable dental operation shall be provided to the board in writing prior to the provision of such services;</li> </ol> <p><i>While the initial application will include information about practitioners who will be providing services at a location, the clinic may employ different practitioners as it moves from location to location. It is necessary for the Board to maintain a listing of who will be working at a particular location prior to the operation of the clinic to ensure that they are appropriately authorized to practice.</i></p> <ol style="list-style-type: none"> <li>3. The address or location of each place where the mobile dental facility or portable dental operation will provide dental services and the dates on which such services will be provided. Any additional locations or dates for the provision of dental services in a mobile dental facility or portable dental operation shall be provided to the</li> </ol>

		<p>board in writing prior to the provision of such services.</p> <p><i>The address or location where services are being provided will vary as the clinic operation moves about the state, so the Board must be informed about its location as schedules are made.</i></p> <p>Subsection B clarifies that the information about locations, practitioners in the clinics and the address of record is public information.</p> <p>Subsection C requires that an application for registration of a mobile dental facility or portable dental operation include certain certifications:</p> <ol style="list-style-type: none"> <li>1. That there is a written agreement for emergency follow-up care for patients to include identification of and arrangements for treatment in a dental office which is permanently established within a reasonable geographic area;</li> </ol> <p><i>Once a child (or adult) has been seen at a mobile clinic, that facility will move on to another location. To ensure that a patient is not left with an unresolved need for emergency care, there must be a written agreement with dentists in the area who are willing to take patients seen at a mobile clinic.</i></p> <ol style="list-style-type: none"> <li>2. Certification that the facility or operation has access to communication facilities that enable the dental personnel to contact assistance in the event of a medical or dental emergency;</li> </ol> <p><i>The requirement for communication facilities to contact assistance is essential to deal with a medical or dental emergency.</i></p> <ol style="list-style-type: none"> <li>3. Certification that the facility has a water supply and all equipment necessary to provide the dental services to be rendered therein;</li> </ol> <p><i>The Board did not choose to specify what equipment must be a part of or contained within a mobile clinic (as other states have done in their regulations), but this rule does specify that there must be a water supply and all equipment necessary to provide whatever dental care is being rendered.</i></p> <ol style="list-style-type: none"> <li>4. Certification that the facility or operation conforms to all applicable federal, state and local laws, regulations and ordinances dealing with radiographic equipment, sanitation, zoning, flammability and construction standards; and</li> </ol>
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			<p>5. Certification that the applicant possesses all applicable city or county licenses or permits to operate the facility or operation.</p> <p><i>Finally, the Board is not requiring submission of copies of all such permits, licenses, etc. (as other states have done in their regulations), but does require that the facility certify that is compliant with all applicable ordinances, laws and regulations.</i></p> <p>Subsection D makes it clear that registration may be denied or revoked for a violation of provisions of § 54.1-2706 of the Code of Virginia.</p> <p><b><i>Changes from the emergency regulations:</i></b></p> <p>In subsection A, the emergency regulations require the clinic or operation to provide information on licensees practicing in the clinic on a particular date or dates and the locations where the clinic will provide dental services <i>at least 10 days in advance</i>. Apparently that is not always possible and creates an unnecessary barrier to the provision of services. The Board does need to have that information in writing prior to the provision of services, but it is not necessary to have it 10 days in advance.</p> <p>Subsection B was added to clarify that the information in subsection A about locations, practitioners in the clinics and the address of record is public information.</p>
n/a	342	Establishes the requirements for operation of a clinic or operation	<p>Subsection A requires that a copy of the registration of the facility or operation and copies of the licenses of the dentists and dental hygienists or registrations of the dental assistants II shall be displayed in plain view of patients.</p> <p><i>To ensure accountability for the services being provided, it is necessary for patients to know whether the mobile facility is appropriately registered and the identity of the licensees providing care in that facility.</i></p> <p>Subsection B requires that prior to treatment, the facility or operation shall obtain written consent from the patient or if the patient is a minor or incapable of consent, his parent, guardian or authorized representative.</p> <p><i>Mobile dental clinics are used most often at local schools; it is essential that a parent or guardian be aware of and give consent to treatment. In some</i></p>

		<p><i>cases, a portable dental operation is taken to nursing homes, so the patient may be incapable of consent, which must then come from an authorized representative of the patient.</i></p> <p>Subsection C requires that each patient be provided with an information sheet or if the patient, his parent, guardian or authorized agent has given written consent to an institution or school to have access to the patient’s dental health record, the institution may be provided a copy of the information. At a minimum, the information sheet shall include:</p> <ol style="list-style-type: none"> <li>1. Patient name, date of service and location where treatment was provided;</li> <li>2. Name of dentist and dental hygienist who provided services;</li> <li>3. Description of the treatment rendered and tooth numbers, when appropriate;</li> <li>4. Billed service codes and fees associated with treatment;</li> <li>5. Description of any additional dental needs observed or diagnosed;</li> <li>6. Referral or recommendation to another dentist if the facility or operation is unable to provide follow-up treatment; and</li> <li>7. Emergency contact information.</li> </ol> <p><i>In every state where mobile clinics are regulated, there is a requirement for an information sheet to be given to patients at the conclusion of the appointment (in the case of a child, the parent may consent for the sheet to be given to the school for the school to then give to the parent). A patient must have that information because a patient record is not readily available as it would be from a local dentist in case additional problems occur or follow-up treatment is needed.</i></p> <p>Subsection D requires patient records to be maintained, as required by 18VAC60-20-15, in a secure manner within the facility or at the address of record listed on the registration application. Records shall be made available upon request by the patient, his parent guardian or authorized representative and shall be available to the board for inspection and copying.</p> <p>Subsection E specifies that the practice of dentistry</p>
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			<p>and dental hygiene in a mobile dental clinic or portable dental operation shall be in accordance with the laws and regulations governing the practice.</p> <p><i>The same standard of care applies to the practice of dentistry or dental hygiene regardless of the setting in which dental care is provided.</i></p>
n/a	352	Sets out the entities that are exempt from the requirements for registration	<p>Those entities that are exempt include:</p> <ol style="list-style-type: none"> <li>1) federal, state and local governmental agencies; and</li> <li>2) Dental treatment which is provided without charge to patients or to any third party payer.</li> </ol> <p><i>The law provides an exception for “those operated by federal, state or local governmental agencies, or by other entities deemed appropriate for exemption by the Board of Dentistry.” The Board has exempted through regulation those clinics or operations that are set up periodically to provide free dental care to underserved populations, which would include the volunteer projects operated by the Virginia Dental Association (VDA).</i></p> <p><b>Changes from the emergency regulations:</b> The Board eliminated the language about treatment provided without charge “and which is not provided on a regular basis (recurring at fixed or uniform intervals).” Volunteer clinics, such as those sponsored by the VDA, may occur at regular intervals, and the Board did not want to hinder those activities.</p>